



FOR US POSTAL SERVICE DELIVERY:

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August 22, 2001

Arthur W. Nienhuis, M.D.
Director
St. Jude Children's Research Hospital
332 North Lauderdale Street
Memphis, TN 38105-2794

**RE: Human Research Subject Protections Under Multiple Project Assurance
(MPA) M-1013**

Dear Dr. Nienhuis:

The Office for Human Research Protections (OHRP) has reviewed St. Jude Children's Research Hospital's (SJCRH's) July 16, August 7, and August 9, 2001 reports which were submitted in response to OHRP's July 13, 2001 letter regarding SJCRH's systemic protections for human subjects.

Based upon its review, OHRP finds that SJCRH has completed the actions required by OHRP in its July 13, 2001 letter. In specific, OHRP notes the following:

(1) OHRP finds that SJCRH has developed and implemented a satisfactory corrective action plan to ensure prompt reporting to the IRB, appropriate institutional officials and OHRP of all unanticipated problems involving risks to subjects or others. In particular, OHRP acknowledges that (a) you personally made presentations to institutional officials, investigators, and research personnel that addressed the reporting requirements under Department of Health and Human Services regulations for the protection of human subjects; (b) through your presentations and written communications to all SJCRH staff, you have encouraged open channels of communication where all SJCRH personnel are encouraged to communicate directly to the IRB any concerns regarding human subject protections; and (c) in order to provide on-going training about these matter, Dr. Don Workman, the Administrator of the SJCRH IRB, is developing a videotape presentation about the requirements for reporting promptly to the IRB and institutional officials any unanticipated problems involving risks to subjects or others.

(2) OHRP finds that the SJCRH IRB has conducted a thoughtful and substantive review of the issues related to interpretation of EEGs performed on research subjects. Furthermore, OHRP acknowledges that the IRB has issued appropriate recommendations to research investigators and institutional officials in response to the delayed documentation of EEG interpretations in the context of research.

As a result of the above determinations, OHRP is removing, effective immediately as of the date of this

letter, the restriction on the SJCRH Multiple Project Assurance (MPA M-1013) and is closing its compliance oversight investigations of SJCRH. Of course, OHRP must be notified should new information be identified which might alter the above determinations.

OHRP appreciates the commitment of SJCRH to the protection of human subjects. Please contact me if you have any questions.

Sincerely,

Michael A. Carome, M.D.
Director, Division of Compliance Oversight

cc: Chairman, Board of Governors, SJCRH
Dr. Victor M. Santana, IRB Chair, SJCRH
Dr. Joseph Mirro, Chief Medical Officer, SJCRH
Dr. Don Workman, IRB Administrator, SJCRH
Dr. Stephen Thompson, SJCRH
Dr. Amar Gajjar, SJCRH
Dr. Raymond Mulhern, SJCRH
Commissioner, FDA
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Dr. Jeffrey Cohen, OHRP
Mr. Barry Bowman, OHRP